K033109
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510(k) Summary

MAR 2 3 2004

Date
February 16, 2004

Submitter
Scient'x
Batiment Calypso
Parc Ariane 3
78284 Guyancourt
FRANCE

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Vertebral Body Replacement Device

Classification name
Vertebral Body Replacement Device per 21 CFR section 888.3060

Equivalent Device
The Ellys and Aurys VBR are similar in design, material, use of supplemental fixation and indications as the PEEK Tertris® (Signus Medical, K031757), and Verte-Stack™ (Medtronic, K021791).

Device Description
The Ellys components are kidney shaped and are used in pairs for full corpectomy or individually when only a portion of the vertebral body is resected. The interior of the spacers is open to provide space for bone graft. The implant is always implanted in the vertical position. These components are available in various heights (8mm-150mm) to accommodate the variability of patient size, anatomic variation, and the location and the size of the vertebral body defect. The superior and inferior surfaces of these components have ridges to interface with the vertebral endplates to resist rotation and migration. The body has a multitude of holes to allow additional impaction of bone graft.

The Aurys components are trapezoidal in cross section and are used singly. The interior of these components have three hollow compartments that run the vertically and are provided for the placement of bone graft. Like the Ellys the Aurys components are also available in various heights (9mm-150mm) and have angled ends to match the angle of the vertebral endplates. The ends have ridges similar to the Ellys to interface with the vertebral endplates. There are also holes evenly spaced on the medial/lateral surfaces to complete bone graft impaction after insertion.

Both the Ellys and Aurys components are fabricated from pure poly(ether ether ketone) (PEEK). This material closely matches the modulus of elasticity of cortical bone, improving the biomechanical interface and reducing the stress shielding effect. They are fully radio-translucent, which enables optimum follow-up with diagnostic imaging, as the interbody fusion progresses. Two metal wires at the opposite ends of the spacers allow radiological confirmation of the cage position post operatively.

Intended Use
Ellys and Aurys Vertebral Body Replacements are vertebral body replacements for use in the lumbar and thoracic spine (T1-L5) to replace a damaged, collapsed or unstable vertebral body due to tumor or trauma (i.e. fracture). These are not stand-alone devices, ISOBAR Ø6.2 Hemispherical Screws with Offset Clamps and Ø5.5 Rods must be utilized to enhance the stability of the reconstruction in skeletally mature patients following full or partial corpectomy.

Summary Nonclinical Tests
Testing was performed per ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Scient'x, Inc.
C/o Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K033109
Trade Name: Ellys and Aurys Vertebral Body Replacements
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: February 16, 2004
Received: February 23, 2004

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K033109

Device Name: Ellys and Aurys Vertebral Body Replacements

Indications for Use:

Ellys and Aurys Vertebral Body Replacements
Indications for Use
Amended

Ellys and Aurys Vertebral Body Replacements are vertebral body replacements for use in the lumbar and thoracic spine (T1-L5) to replace a damaged, collapsed or unstable vertebral body due to tumor or trauma (i.e. fracture). These are not stand-alone devices, ISOBAR Ø6.2 Hemispherical Screws with Offset Clamps and Ø5.5 Rods must be utilized to enhance the stability of the reconstruction in skeletally mature patients following full or partial corpectomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

(Division Sign-off)
Division of General, Neurological and Restorative Devices

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033109